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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,508	10/12/2000	Scott A. Ruddell	DI-5654	9098

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

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16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/689,508	RUDDELL ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35,38-73 and 95-115* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35,38-48,51-58,60-66,68-73,95-101,103-108 and 110-115* is/are rejected.

7)☒ Claim(s) *49, 50, 59, 67, 102 and 109* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1 and 3-35, 38-42, 44-48, 51-58, 60-66, 68-71, 73, 95-97, 99-101, 103-108, 11-113 and 115 are rejected under 35 U.S.C. 102(b) as being anticipated by Zakko, 5,527,274.

As to claim 1, Zakko discloses a tube (see Figure 4) having an implantable portion (i.e., distal portion of tube) extending from an external patient portion (i.e., proximal portion of tube), the implantable portion having a curved segment between the external patient portion and a distal end of the implantable portion; a first lumen (54) extending through the tube from a first lumen port in the external patient portion (i.e., infusion port in the proximal end of tube) to a first lumen port (60) in the curved segment of the implantable portion; and a second lumen (50) extending through the tube from a second lumen port in the external patient portion (i.e., aspiration port in the proximal end of tube) to a second lumen port (62) in the implantable portion, the second lumen port in the implantable portion being spaced away from the curved segment, see also column 17, lines 43-50.

As to claim 3, the first lumen port in the curved segment comprises a plurality of openings (60) at an outer radial surface of the curved segment.

As to claims 4, 7 and 10, the plurality of openings are substantially round holes, see Figure 5.

As to claims 5, 8 and 11, the plurality of openings are considered slots, see Figure 5.

As to claim 6, the implantable portion has a coiled shape at the distal end, see Figure 4.

As to claim 9, the implantable portion has a substantially straight shape at the distal end, see Figure 5.

As to claim 12, the tube is a single tube having a septum between the first and second lumens, see Figure 3.

As to claim 13, the first lumen port (60) in the curved segment is a patient inflow port, see column 17, lines 45-47.

As to claim 14, the second lumen port (62) in the implantable portion is a patient outflow port, see column 17, lines 48-50.

As to claim 15, the first lumen (54) terminates prior to the distal end of the implantable portion, see column 17, lines 33-34, and column 18, lines 1-2.

As to claim 16, Zakko discloses a connection section having an inflow port (one of the proximal ports in Figure 4) to a patient inflow lumen, and an outflow port (one of the proximal ports in Figure 4) to a patient outflow lumen; a patient inflow section extending from the connection section and having a patient inflow opening (60) to the

patient inflow lumen; a separation section extending from the patient inflow section; and a patient outflow section extending from the separation section and having a patient outflow opening (62) to the patient outflow lumen wherein the patient inflow section (i.e., the section extending from the connection section) is located closer to a position on the connection section that is suitable for attachment to a patient's body than to the patient outflow section (i.e., the distal section of the tube.)

As to claim 17, when the catheter is in a substantially unstressed condition, the connection section is substantially straight, the patient inflow section is curved, and the separation section is substantially straight.

As to claim 18, the patient outflow section is coiled.

As to claim 19, the patient outflow section is substantially straight.

As to claim 20, the patient inflow section is considered an uppermost portion of an implantable portion of the catheter and the patient outflow section is considered a lowermost portion of the implantable portion of the catheter.

As to claim 21, the connection section, patient inflow section, separation section, and patient outflow section further comprise a flexible tube having an internal septum between the patient inflow and outflow lumens, see Figure 3.

As to claim 22, the patient inflow section has a curved shape, see Figure 5.

As to claims 23 and 40, the patient inflow opening to the patient inflow lumen is in a direction away from the patient outflow opening to the patient outflow lumen.

As to claims 24, 41 and 42, the catheter comprises a single tube having the patient inflow (54) and outflow (50) lumens, and wherein the tube transitions from

having both the patient inflow and outflow lumens to having only the patient outflow lumen (50) at a location between the patient inflow section and a distal catheter end.

As to claim 25, Zakko discloses a flexible single tube having first and second lumens, the first lumen (54) extending from a first fluid opening (one of the proximal openings in Figure 4) to a second fluid opening (60), the second lumen (50) extending from a third fluid (one of the proximal openings in Figure 4) opening to a fourth fluid opening (62), the first and third fluid openings being in an external patient portion of the catheter (i.e., proximal portion of the catheter), the second and fourth fluid openings being in an implantable portion of the catheter (i.e., distal portion of the catheter) and spaced significantly apart from each other, the implantable portion of the catheter have a generally non-linear shape, see Figure 5.

As to claim 26, the second fluid opening is located at a non-linear shaped section of the implantable portion, see Figure 5.

As to claim 27, the second (60) and fourth (62) fluid openings are separated by a substantially linear tube section which is absent fluid openings to an exterior of the catheter, see Figure 5.

As to claim 28, the second fluid opening (60) is located at a vertically uppermost portion of the implantable portion and the fourth fluid opening (50 and 62) is located at a vertically lowermost portion of the implantable portion, see column 18, lines 1-2.

As to claim 29, Zakko discloses a substantially straight connection section (i.e., proximal portion of catheter); a non-linear patient inflow section extending from the connection section (i.e., portion of catheter near 60); a separation section extending

from the patient inflow section (i.e., portion of catheter in between 60 and 62); a patient outflow section (i.e., portion of catheter near 62) extending from the separation section; a patient inflow lumen (54) extending from the connection section to the patient inflow section; and a patient outflow lumen (50) extending from the connection section to the patient outflow section.

As to claim 30, the separation section has a substantially straight shape, see Figure 5.

As to claim 31, the patient outflow section has a coiled shape, see Figure 4 or 5.

As to claim 32, the patient inflow section has a curved shape of about 180 degrees. The catheter is capable of having a shape of about 180 degrees, see column 4, lines 37-38, and thus the catheter is considered to have a curved shape of about 180 degrees, as claimed by Applicant.

As to claim 33, Zakko discloses a dialysis machine connection section (i.e., proximal section of catheter) having fluid ports to first and second lumens; a non-linear section (i.e., section of catheter near 60 in Figure 4) extending from the connection section and having a fluid port to the first lumen; a separation section (i.e., section of catheter in between 60 and 62) extending from the non-linear section; and a distal end section (i.e., section of catheter near 62) extending from the separation section and having a fluid port to the second lumen, wherein the fluid port of the non-linear section faces away from the distal end section when the catheter is implanted in a patient.

As to claim 34, the first lumen is a patient inflow lumen and the second lumen is a patient outflow lumen, see column 17, lines 43-50.

As to claim 35, the non-linear section has a curved shape and the fluid port in the non-linear section is considered pointed in a direction opposite the fluid port in the distal end section, see Figure 4.

As to claims 38, 47, 48, 51, 52, 56, 57, 62, 64, 65, 66, 68, 69, 103-108, 110-113, and 115, the first lumen is in a side-by-side arrangement relative to the second lumen, the catheter is capable of being positioned and arranged such that when in use in a peritoneal cavity fluid flows out of the first lumen in an upper area of the peritoneal cavity and into the second lumen in a lower area of the peritoneal cavity.

As to claim 39, 45, 46, 54, 55, 63, 70, 71, 73, 95-97, 100, and 102, the catheter is capable of being used with an automated peritoneal dialysis system.

As to claim 53, 58, 60, 61 and 99, the upper portion is a preformed non-linear portion, see Figure 4 or 5.

As to claims 44 and 99, the outflow portion is located at the distal portion of the catheter, and the inflow portion is located at the proximal portion of the catheter. The outflow portion is located closer to the distal end of the catheter than the inflow portion.

2. Claims 43, 72, 98, and 114 are rejected under 35 U.S.C. 102(b) as being anticipated by Sommercorn et al., 4,543,087

Sommercorn et al. discloses a catheter having a first lumen (26), a first fluid opening (38) to the first lumen, a second lumen (12), and a second fluid opening (34) to the second lumen defined at a second location along an implantable portion different from the first location of the first fluid opening, wherein the first and second lumens are

so positioned and arranged when the implantable portion is implanted in a peritoneal cavity that the first lumen is side-by-side the second lumen and the fluid openings are at generally opposite portions of the peritoneal cavity. Also, the first and second lumens have different lengths, see Figure 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zakko, 5,527,274, in view of Moncrief et al., 5,057,075.

Zakko discloses the invention substantially as claimed, see above. However, Zakko does not disclose an implant cuff.

Moncrief et al. discloses a catheter for implantation having a cuff (24) that is amenable to in-growth of living tissue, see column 2, lines 19-25. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an implant cuff on the Zakko device for implanting the catheter into a living body, as taught by Moncrief et al.

Allowable Subject Matter

4. Claims 49, 50, 59, 67, 102, 109 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Examiner has considered the arguments and the claims as amended. However, the references are still applicable (see rejections above.)

The arguments have been considered but they are not persuasive.

Applicant argues on page 24 that amended claim 1 overcomes the prior art. However, Examiner asserts that the second lumen port (62)is spaced away from the curved segment (i.e., distal portion of tube.)

Claims 16, 25, 33, 44, likewise, do not overcome the art of record, (see new rejections above.)

Moreover, as to Claim 33, the term "faces away" in line 9 is vague and is thus interpreted broadly.

Applicant also argues that Applicant's catheters space apart the inflow and outflow apertures to create a ranging flow across the peritoneal cavity, whereas Zakko spaces the inflow and outflow apertures close together for localized contact, see page 24. In response, Examiner asserts that recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the

prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Mary E. Ceperley

MARY E. CEPERLEY
PRIMARY EXAMINER
AU1641

A.L.